REMARKS

Claims 1, 8, 9, 24 and 25 are presently amended herein. Claims 1-4, 6-19 and 21-26 are presently pending and claims 14-19 and 21-23 were previously withdrawn from consideration. Applicants appreciate the Examiner's characterization of claims 6 and 7 as allowable. The amendments to the claims are fully supported by the specification and original claims. Specifically, claims 1, 9, 24 and 25, have been amended to more clearly set forth the fact that a substantially amount of GMP is adsorbed by the anionic resin and that the treated liquid material is substantially free of GMP, since it is adsorbed onto the resin. These amendments are supported by the specification, for example, at page 4, lines 6-8, page 7, lines 20-22, and pages 8-13--the examples. Applicants provide working examples in the specification, Examples 1-4, wherein applicants adsorbed substantial amounts of GMP onto the anionic resin (yielding 82%, 80%, and 80% relative to the starting GMP when eluted from the resin), which resulted in a treated liquid that did not contain a substantial amounts of GMP (91%, 89%, and 85% of GMP being removed as tested by HPLC). Furthermore, one skilled in the art would understand that a substantial amount of GMP is over 50% of the GMP in the material being treated, which is supported by Applicants working examples as stated above. Claim 8 was amended to clarify the claim as requested by the Examiner. No new matter has been added by these amendments. Entry of the amendments at this time is therefore respectfully requested.

Claim 8 was rejected under 35 USC §112, second paragraph, as being indefinite for the reasons stated on pages 2-3 of the Office Action.

Applicants have amended claim 8 to delete the term "between." While Applicants do not agree with the Examiner's reasoning here, especially in view of the fact that over 60,000 patents have issued with the phrase "between about" in the claims, Applicants have amended the claim to delete the term "between" in an effort to expedite the allowance of the present application, and do not believe that the amendment narrows the claim in any way. In view of the amendment, Applicants respectfully request that this rejection be removed.

Claims 1-4, 9-13, and 24-25 were rejected under 35 USC §103 as being unpatentable over U.S. Patent No. 5,434,250 to Shimatani ("Shimatani"), or Shimatani in view of Scopes, *Protein Purification*, pages 68-75, 1982 ("Scopes"), for the reasons stated on pages 3-7 of the Office Action.

Independent claims 1, 9, 24 and 25 have been amended to require that a substantial amount of GMP is adsorbed onto the anionic resin and also that the treated liquid material obtained does not contain substantial amounts of GMP, as the GMP has been

adsorbed onto the anionic resin. These amendments were made to further clarify that Applicants' process "removes" GMP from the deionized lactic raw material by "adsorbing" substantial amounts of GMP onto the anionic resin and not by some other means.

In contrast, Shimatani discloses and claims a process for obtaining sialic acids by contacting whey with a cation exchanger to produce an exhanger-passed solution. The exchanger passed solution is high in α-La -- containing substantial amounts of GMP. This is evident by the fact that the Shimatani process requires that the exchanger passed solution must be further concentrated by using ultrafiltration "in order to efficiently remove GMP from the exchanger-passed solution and to enhance the α-La content." *See* Shimatani at Col. 3, line 68 to Col. 4, line 2. Therefore, the GMP in Shimatani is not being adsorbed onto the anionic resin as required by the presently pending claims.

Furthermore, the treated liquid material (exchanger passed solution) in Shimatani contains substantially amount of GMP, which requires additional steps to remove, such as ultrafiltration and lowering the pH. *See* Shimatani at Col 2, lines 25-30 and Col. 3, line 68 to Col. 4, line 2. The presently pending claims specifically require that the treated liquid material does not contain substantial amounts of GMP. Shimatani does not teach or suggest this.

There is no motivation in Shimatani to develop Applicants' presently claimed invention either, as the intent of teachings of Shimatani is to enhance the α-La content and to rid the composition of GMP through ultrafiltration. The dissimilar purposes of Shimatani's process and Applicants' process are evidenced in the divergent steps required by each process and the different end products produced by each. Without at least some suggestion of the step of adsorbing substantial amounts of GMP onto the anionic resin to obtain a treated liquid material that does not contain substantial amounts of GMP, Shimatani cannot make obvious Applicants invention.

Scopes does not remedy the deficiencies of Shimatani. As stated by the Examiner, Scopes make no mention of GMP at all. Scopes does not teach or suggest Applicants' presently claimed invention that allows the selective separation of GMP from other components contained within lactic raw materials in a single operation, on an industrial scale, and in high yields. Nothing in Scopes would motivate one skilled in the art to modify the Shimatani method to obtain Applicants' presently claimed method of adsorbing a substantial amount of GMP onto the anionic resin to obtain a treated liquid material that does not contain substantial amounts of GMP.

The limitations set forth in the claims cannot be set aside in order to determine obviousness. As pointed out above, the limitations of Applicants' presently claimed invention are not taught or suggested by Shimatani and/or Scopes, therefore the references alone or in combination cannot make Applicants' presently claimed invention obvious. Applicants' therefore request that this rejection be withdrawn.

Claims 1-4, 9-13, and 24-25 were rejected under 35 USC §103 as being unpatentable over Shimatani in view of Marshall, *Food Research Quarterly*, Vol. 51, 1991 ("Marshall"), and further in view of Scopes, for the reasons stated on pages 7-9 of the Office Action.

As discussed above, Shimatani fails to teach or suggest the steps of Applicants' process, specifically the steps of **adsorbing a substantial amount of GMP onto the anionic resin** to obtain a treated liquid material **that does not contain substantial amounts of GMP**. The Examiner also admits that "Shimatani does not disclose a method of chromatograph in which GMP is retained on a cation exchange column."

Marshall also fails to remedy the deficiencies of Shimatani. Marshall does teach the fact that GMP is a useful peptide, but fails to teach or suggest a method of obtaining GMP.

Furthermore, Scopes does not remedy the deficiencies of Shimatani and/or Marshall. Scopes simply discusses theories behind ion exchange techniques. Scopes does not even mention GMP. Nothing in Scopes would motivate one to modify the method taught in Shimatani in a way that would result in Applicants presently claimed invention that specifically requires adsorbing a substantial amount of GMP onto the anionic resin to obtain a treated liquid material that does not contain substantial amounts of GMP.

Due to the fact that Shimatani, Marshall, and Scopes do not suggest alone or in combination the steps of Applications' process, this rejection for obviousness should also be withdrawn.

Claims 1-4, 9-13, and 24-25 were rejected under 35 USC §103 as being unpatentable over U.S. Patent No. 5,278,288 to Kawasaki ("Kawasaki") in view of Scopes, for the reasons stated on pages 9-10 of the Office Action.

Kawasaki is directed to a process of producing κ-casein glycomacropeptides. The process of Kawasaki involves the steps of contacting milk raw materials containing the 1/2 casein glycomacropeptide with a **cation exchanger** and collecting a fraction which **does not adsorb** on the cation exchanger to obtain the κ-casein glycomacropeptides. *See* Kawaski at Col. 8, lines 1-11 and Abstract. The process of Kawasaki specifically teaches and requires

that the fraction **not adsorbed** on the ion exchanger (the filtrate) should be collected as it contains the κ-casein glycomacropeptides.

In contrast, Applicants' process, as explained in more detail above, requires **adsorbing a substantial amount of GMP** onto the **anionic resin** to obtain a treated liquid material that **does not contain substantial amounts of GMP**. Kawasaki does not teach or suggest these steps.

Scopes does not remedy the deficiencies of Kawasaki. Scope is directed to theories behind ion exchange techniques. Scopes does not even mention GMP.

For these reasons, Kawasaki, alone or in combination with Scopes cannot make obvious Applicants' invention. Applicants therefore respectfully request that this rejection should also be withdrawn.

Claims 25-26 were rejected under 35 USC §103 as being unpatentable over Shimatani in view of U.S. Patent No. 5,063,203 to Drouet ("Drouet"), for the reasons stated on page 10 of the Office Action.

As explained above in detail above, Shimatani does not teach or suggest Applicants' presently claimed process. The reference fails to teach the steps of Applicants' presently claimed process, in particular the step of **adsorbing a substantial amount of GMP** onto the **anionic resin** to obtain a treated liquid material that does not contain substantial amounts of GMP.

Drouet does nothing to remedy the deficiencies of Shimatani. Drouet simply discloses that GMP inhibits thrombosis, but does not disclose any process of obtaining GMP.

Therefore, Applicants respectfully request that the 35 USC §103(a) rejection be withdrawn.

Claims 25-26 were rejected under 35 USC §103 as being unpatentable over Kawasaki in view of Scopes, and further in view of Drouet, for the reasons stated on pages 10-11 of the Office Action.

As explained above in detail, Kawasaki nor Scopes teach or suggest Applicants' presently claimed process, which expressly requires that a substantial amount of GMP be adsorbed onto the anionic resin and that treated liquid material obtained does not contain substantial amounts of GMP. The references, therefore fail to teach or suggest the steps of Applicants' presently claimed process.

Drouet does nothing to remedy the deficiencies of Kawasaki and Scopes. Drouet simply discloses that GMP inhibits thrombosis, but does not disclose any process of obtaining GMP.

Due to the fact that Shimatani, Scopes, and Drouet do not suggest, alone or in combination, the steps of Applicants' process, Applicants respectfully request that the 35 USC §103(a) rejection be withdrawn.

In view the foregoing remarks and amendments it is believed that the entire application is now in condition for allowance. Should any issues remain please call Allan Fanucci at (212) 294-3311 or Rodney Fuller at (202) 371-5838 in order to expedite the allowance of all the claims in this application.

Respectfully submitted,

Date: 4/01/09

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